DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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King & Spalding
Attention: Ellen Armentrout
1730 Pennsylvania Avenue, N.W.
Washington, D.C. 20006-4706

Docket No. 99P-2798/CP1

Dear Ms. Armentrout:

This is in response to your petition filed on August 16, 1999, requesting permission to file an Abbreviated New Drug Application (ANDA) for the following drug product: Oxycodone Hydrochloride and Acetaminophen Tablets, 10mg/500mg. The listed drug product to which you refer in your petition is Oxycodone Hydrochloride and Acetaminophen Tablets 10mg/650mg, manufactured by Endo Pharmaceuticals, Inc.

Your request involves a change in strength of the Acetaminophen component from that of the listed combination drug product (i.e., from 650 mg to 500 mg). The change you request is the type of change that is authorized under the Act.

We have reviewed your petition under Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (Act) and have determined that it is approved. This letter represents the Agency's determination that an ANDA may be submitted for the above-referenced drug product.

Under Section 505(j)(2)(C)(i) of the Act, the Agency must approve a petition seeking a strength which differs from the strength of the listed drug product unless it finds that investigations must be conducted to show the safety and effectiveness of the differing strength.

The Agency finds that the change in strength for the specific proposed drug product does not pose questions of safety or effectiveness because the uses, and route of administration of the proposed drug product are the same as that of the listed drug product. The Agency concludes, therefore, that investigations are not necessary in this instance. In addition, if shown to meet bioavailability requirements, the proposed drug product can be expected to have the same therapeutic effect as the listed reference drug product.

When an ANDA is submitted for your proposed drug product, the proposed labeling should reflect the maximum number of tablets per day that can be administered for your proposed drug products (i.e., 8 tablets). The total daily dose of the acetaminophen component should not exceed the maximum total daily dose for adults of 4000 mg established by the Agency for its safe and effective range. Please refer to the Tentative Final Monograph for Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use (53 FR 46204, November 16, 1988).

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The approval of this petition to allow an ANDA to be submitted for the above-referenced drug product does not mean that the Agency has determined that an ANDA will be approved for the drug product. The determination of whether an ANDA will be approved is not made until the ANDA itself is submitted and reviewed by the Agency.

To permit review of your ANDA submission, you must submit all information required under Sections 505(j)(2)(A) and (B) of the Act. To be approved, the drug product will, among other things, be required to meet current bioavailability requirements under Section 505(j)(2)(A)(iv) of the Act. We suggest that you submit your protocol to the Office of Generic Drugs, Division of Bioequivalence for this drug product prior to the submission of your ANDA. During the review of your application, the Agency may require the submission of additional information.

The listed drug product to which you refer in your ANDA must be the one upon which you based this petition. In addition, you should refer in your ANDA to the appropriate petition docket number cited above, and include a copy of this letter in the ANDA submission.

A copy of this letter approving your petition will be placed on public display in the Dockets Management Branch, Room 1061, Mail Stop HFA-305, 5630 Fishers Lane, Rockville, MD 20852.

Sincerely yours,

Gary J. Buehler
Acting Director
Office of Generic Drugs
Center for Drug Evaluation and Research